K032810

DEC - 5 2003

510(k) SUMMARY

DURAN PRODUCT FAMILY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA and CFR 807.92.

I SUBMITTER INFORMATION

Company Name:	Medtronic Heart Valves (Medtronic)
Company Address:	8299 Central Avenue N.E. Minneapolis, MN 55432
Company Phone:	(763) 514-6600
Company Facsimile:	(763) 514-6775
Contact Person:	Julie Sherman Regulatory Affairs Manager
Date Summary Prepared:	September 8, 2003

II DEVICE IDENTIFICATION

Trade/Proprietary Name:

Duran Band (Model H607H)
Duran Ring and Band (Models 610R and 610B)
Duran AnCore Ring and Band (Models 620R and 620B)
Duran AnCore Ring and Band with Chordal Guide (Models 620R and 620B)

21 CFR Reference:	870.3800
21 CFR Common Name:	Ring, Annuloplasty
Classification:	Class II
Panel:	CV (74) KRH

III IDENTIFICATION OF PREDICATE DEVICE

Device	Model #	510(k) Number
Duran Ring	H608H	K980534

The 510(k) also includes references to the following marketed devices:

Device	Model #	510(k) Number
Duran Ring	H601H	K893678
Posterior Band	607	K960356
CG Future Band	638B	K011395

IV DEVICE DESCRIPTION

The Duran product family (including the Duran products listed in Section II – DEVICE IDENTIFICATION), consist of permanent, implantable, flexible annuloplasty rings or bands made of polyester fabric with a 3-mm cross-section. A silicone marker, impregnated with barium sulfate enables radiographic visualization. The individual ring and band sizes range from 23mm to 35mm, in two-millimeter increments.

The Duran products are used with associated accessories that include a holder, handle and sizers. The ring or band is provided on a holder to facilitate implantation of the device. The sizers are used to assess appropriate ring or band size and the handle interfaces with the holder to allow for proper positioning of the ring or band.

V DESCRIPTION OF INDICATIONS FOR USE

The devices in the Duran product family (including the Duran products listed in Section II) are indicated for the reconstruction and/or remodeling of pathological mitral and tricuspid valves.

Note: The Chordal Guide feature of the Duran AnCore Ring and Band with Chordal Guide (Models 620R and 620B) is indicated only for chordal replacement surgery of pathological mitral valves.

VI SUBSTANTIAL EQUIVALENCE

The Duran products listed in Section II are substantially equivalent to the predicate, Duran Ring (Model H608H). The implantable portion of the devices (the annuloplasty ring or band) are identical to the previously cleared Duran Ring (Model H608H), only the packaging and accessories (including holder, handle and sizers) have changed. An additional ring and band size (23mm) was added for the Duran AnCore Ring and Band and the Duran AnCore Ring and Band with Chordal Guide (Models 620R and 620B), however this size is dimensionally the same as the smallest sized CG Future Band (Model 638B)(K011395) previously cleared by FDA.

The devices have the same indications for use, repair of mitral and tricuspid valves. (Note: The Chordal Guide feature of the Duran AnCore Ring and Band with Chordal Guide (Models 620R and 620B) is indicated only for chordal replacement surgery of mitral valves.)

The devices are manufactured and sterilized (100% ethylene oxide) using the same process as cleared for the Duran Ring (Model H608H). The packaging is identical to that previously cleared for use with other devices in the Duran product family. The labeling is equivalent to the labeling previously cleared for use with the Duran Ring (Model H608H).

VII TECHNOLOGICAL CHARACTERISTICS

The Duran product family (including the Duran products listed in Section II), consist of permanent, implantable, flexible annuloplasty rings or bands made of polyester fabric with a 3-mm cross-section. A silicone marker, impregnated with barium sulfate enables radiographic visualization. The individual ring and band sizes range from 23mm to 35mm in two-millimeter increments.

Like the predicate device, Duran Ring (Model H608H), the products are indicated for the reconstruction and/or remodeling of pathological mitral and tricuspid valves. (Note: The Chordal Guide feature of the Duran AnCore Ring and Band with Chordal Guide (Models 620R and 620B) is indicated only for chordal replacement surgery of mitral valves.)

VIII PERFORMANCE DATA

The materials used in the manufacture of the Duran products listed in Section II are identical to those used in the predicate device, Duran Ring (Model H608H). The materials include polyester fabric, polyester suture and a silicone marker, impregnated with barium sulfate. These materials have been used to manufacture the Duran products since 1978 with no indication of biocompatibility issues. No changes have been made to the manufacturing or sterilization of this device to warrant new or additional biocompatibility testing of these components. The accessories are made from materials commonly used for medical devices and have been shown to be biocompatible.

Suture pull-out testing was previously conducted on the polyester fabric by looping a 0.009 inch diameter stainless steel wire through the fabric of a Duran Ring, then pulling the wire in a tensile test apparatus until failure. The average pull-out force was 26.90 lbs. Suture pull-out testing was also conducted on an individual fiber. The test consisted of looping only one coarse of the fabric with a 4-0 suture and performing a pull test in a tensile test apparatus. The average pull-out force for this test was 2.61 lbs. No changes were made to the fabric, so this test was not repeated.

The Duran products listed in Section II are sterilized using the same 100% ethylene oxide sterilization process previously qualified for the predicate, Duran Ring (Model H608H). As the result of changes to the packaging and accessories, Medtronic requalified the sterilization cycle for each of the products listed in Section II. The sterilization cycle provides an SAL (Sterility Assurance Level) of 10^{-6}. Sterilant residual levels were tested and meet the requirements of ISO 10993-7 (1995), Biological evaluation of Medical Devices part 7: Ethylene Oxide Sterilization Residuals. Medtronic completes reverification of the Duran products sterilization qualification process on an annual basis.

Biological testing (including bioburden and pyrogen) and manufacturing process controls have been established for the Duran products listed in Section II. The testing and methods used are based on processes established for the predicate device, Duran Ring (Model H608H).

The Duran products are constructed from materials that have already been qualified through Medtronic product shelf-life validation testing. The packaging is identical to packaging previously qualified and cleared by FDA for other Duran products. Therefore, no additional shelf-life testing is required for the devices listed in Section II.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 5 2003

Medtronic Heart Valves
c/o Mr. Phillip Nuerurer
8299 Central Avenue, N.E.
Minneapolis, MN 55432-3576

Re: K032810
Duran Band (Model H607H)
Duran Ring (Model 610R)
Duran Band (Model 610B)
Duran AnCore Ring (Model 620R)
Duran AnCore Band (Model 620B)
Duran AnCore Ring with Chordal Guide (Model 620R)
Duran AnCore Band with Chordal Guide (Model 620B)
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty Ring
Regulatory Class: Class II (two)
Product Code: KRH
Dated: September 8, 2003
Received: September 9, 2003

Dear Mr. Nuerurer:

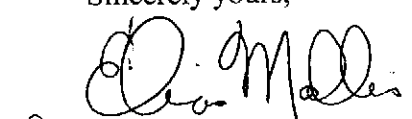
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K03 2 8 1 0

Device Name:

Duran Band (Model H607H)
Duran Ring (Model 610R)
Duran Band (Model 610B)
Duran AnCore Ring (Model 620R)
Duran AnCore Band (Model 620B)
Duran AnCore Ring with Chordal Guide (Model 620R)
Duran AnCore Band with Chordal Guide (Model 620B)

Indications for Use:

The Duran Band (Model H607H), Duran Ring and Band (Models 610R and 610B), the Duran AnCore Ring and Band (Models 620R and 620B) and the Duran AnCore Ring and Band with Chordal Guide (Models 620R and 620B) are indicated for the reconstruction and/or remodeling of pathological mitral and tricuspid valves.

Note: The Chordal Guide feature of the Duran AnCore Ring/Band with Chordal Guide (Models 620R and 620B) is indicated only for chordal replacement surgery of pathological mitral valves.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
Per 21 CFR 801.109

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices

510(k) Number K032810